Oral Phenytoin Shortage

For the current status of drug shortages and discontinuations, refer to Health Product Shortages Canada at https://healthproductshortages.ca.

This document is designed to support health professionals in managing patients prescribed phenytoin during a shortage. The guidance presented here aims to assist health-care providers in navigating drug shortages and selecting suitable alternative therapies; it is not intended as a comprehensive review or clinical practice guideline. Patient assessment requires professional knowledge and judgment beyond the scope of this document. Consult CPS Full Access or other references if required.

TABLE 1: **Oral phenytoin products marketed in Canada**[1]

Product	Strength	DIN	Manufacturer
Phenytoin Sodium			
Dilantin	30 mg 100 mg	00022772 00022780	BGP Pharma ULC
Phenytoin Sodium	100 mg	02460912	AA Pharma Inc.
Phenytoin Free Base			
Dilantin Infatabs	50 mg	00023698	BGP Pharma ULC
Taro-Phenytoin	125 mg/5 mL	02250896	Taro Pharmaceutical Industries Ltd.

Health Canada–Approved Indications for Oral Phenytoin[1]

- Management of generalized tonic-clonic seizures and complex partial (focal) seizures

Off-Label Uses[2]

- Management of unclassified tonic-clonic seizures and partial (focal) seizures

Management Options

During a drug shortage, it is essential to prioritize limited supplies based on clinical need to maximize benefit and minimize harm. Ethical principles of consistency, equity and transparency ensure fair and defensible allocation.

- Avoid starting patients on phenytoin while the shortage persists.
- Do not prescribe or dispense large quantities of phenytoin during the shortage. Stockpiling can result in further exacerbations of shortages and disproportionately impact equity-deserving and low-income groups. Encourage patients to limit refill prescriptions to a 30-day supply and contact their pharmacy or health-care provider in advance of depleting their current supply.

- Ensure timely, clear and transparent communication with patients regarding the shortage and rationale behind any changes to their care plan.

If alternative commercially available phenytoin products are available, consider the following:

- Phenytoin extended-release capsules (30 mg, 100 mg) are labelled as phenytoin sodium. Phenytoin chewable tablets and oral suspensions are labelled as phenytoin free base. **Phenytoin sodium 100 mg is approximately equivalent to 92 mg phenytoin free base.**[3]
- Extended-release capsules may be dosed 1 to 3 times daily; chewable tablets and oral suspensions need to be dosed 3 times daily in adults and 2–3 times daily in children. Once-daily dosing is not appropriate for chewable tablets or oral suspensions.[3]
- A small increase in phenytoin, which may occur with switching of formulations or dosage regimen changes, can result in a significant increase in free serum phenytoin in patients whose metabolic processes and/or serum protein binding sites are at or near saturation.[4] Check serum levels 7–14 days after the switch.

If phenytoin is not available, most patients will need to be switched to an alternative antiseizure medication (ASM). Phenytoin is considered an alternative or additional ASM for focal or unclassified tonic-clonic seizures.[2,5] Recommendations for choosing ASMs vary among guidelines.[6-8]

- First-line monotherapy agents for focal or unclassified tonic-clonic seizures include lamotrigine and levetiracetam.[6]
  - Alternate monotherapy agents include carbamazepine, lacosamide, oxcarbazepine and valproate.[6-8]
- First-line add-on agents include carbamazepine, lacosamide, lamotrigine, levetiracetam, oxcarbazepine and topiramate.[6]
  - Alternative add-on agents include brivaracetam, clobazam, eslicarbazepine, gabapentin, perampanel, phenobarbital, pregabalin, valproate and vigabatrin.[6-8]

When choosing an alternative ASM, consider patient variables such as seizure type, comorbidities, childbearing plans, and treatment history, including previous ASM trials and agents that have been ineffective or poorly tolerated. Consider ASM variables such as potential for drug interactions and side effects, desired titration speed, dosage regimen, cost and patient preferences.

Phenytoin is associated with many drug interactions. Use reputable drug-interaction tools to identify any concurrent medications that will be affected by discontinuation of phenytoin and/or addition of the chosen ASM.

When switching to an alternative ASM, there are no standardized regimens or strong evidence to support different strategies.

- Under ideal circumstances, the chosen ASM is titrated up slowly until a therapeutic dose is achieved, then phenytoin is tapered off over weeks to months.[2,5,9]
  - It may be possible to titrate brivaracetam, lacosamide and levetiracetam more quickly than others.[10]
- If no or limited phenytoin is available, the chosen ASM may need to be titrated up more quickly; the rate of phenytoin taper will likely be dictated by available phenytoin supply.
  - Cross-tapering (titrating up chosen ASM while simultaneously tapering off phenytoin) may need to be considered if there is insufficient phenytoin supply. Note: this leaves the patient more vulnerable to seizures, as there will be a period in which ASM therapy is subtherapeutic.

There may be a small population of patients who may be candidates for ASM discontinuation. Advanced planning is required to ensure candidacy, full discussion with a specialist regarding individual risks versus benefits, and an appropriate taper.[2,5,11] Phenytoin shortage may prompt, but should not preempt, this planning process.

TABLE 2: **Selected antiseizure medications for focal or unclassified tonic-clonic seizures[2]**

Drug	Dosage	Adverse Effects[a]
Brivaracetam	Initial: 100 mg/day PO in 2 divided doses Usual maintenance: 100–200 mg/day PO in 2 divided doses	Sleepiness, nausea, decreased energy, dizziness, irritability, depression
Carbamazepine CR	Initial: 100 mg BID PO Usual maintenance: 800–1200 mg/day in 2 divided doses with meals	Rash, increased liver enzymes, transient neutropenia, hyponatremia
Divalproex	Initial: 250 mg BID PO Usual maintenance: 750–1000 mg/day PO in 2 divided doses	Nausea, alopecia, tremor, weight gain, blood dyscrasias, menstrual irregularities, teratogenicity
Eslicarbazepine	Initial: 400 mg once daily PO x 1 wk Usual maintenance: 800 mg PO once daily Maximum: 1200 mg/day	Dizziness, fatigue, nausea, vomiting, blurred vision, headache, abnormal coordination
Gabapentin	Initial: 300 mg once daily PO Usual maintenance: 900–3600 mg/day PO divided Q6–8H	Tremor, vision changes, gastrointestinal upset
Lacosamide	Initial: 50–100 mg/day PO in 2 divided doses Usual maintenance: 200–400 mg/day PO in 2 divided doses	Dizziness, nausea, ataxia, sedation, PR interval prolongation
Lamotrigine	Initial: 25 mg/day PO Usual maintenance: 100–400 mg/day PO in 2 divided doses	Rash (slow titration required), insomnia
Levetiracetam	Initial: 1000 mg/day PO in 2 divided doses Usual maintenance: 1000–3000 mg/day PO in 2 divided doses	Sleepiness, decreased energy, headache, irritability, depression, psychiatric and behavioural abnormalities
Oxcarbazepine	Initial: 300 mg BID PO Usual maintenance: 1200–2400 mg/day PO in 2 divided doses	Similar to carbamazepine but slightly higher risk of hyponatremia; skin rash cross-reaction with carbamazepine
Topiramate	Initial: 50–100 mg/day PO in 2 divided doses Usual maintenance: 200–400 mg/day PO in 2 divided doses	Cognitive/memory impairment, kidney stones, weight loss, headache, fingers/toes paresthesias, teratogenicity

[a]Virtually all antiseizure medications can produce sedation, fatigue, cognitive impairment, dizziness and ataxia in a dose-dependent fashion.

The information presented here is generalized, and patients should be assessed on an individual basis. Patient assessment requires professional knowledge and judgment beyond the scope of this document. Consult CPS Full Access or other references if required.

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